

201-15278

Anh Nguyen

05/18/2004 07:28 AM

To: NCIC HPV@EPA

CC:

Subject: Fw: Environmental Defense comments on Phosphoric Acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine (CAS# 67763-14-8)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/18/2004 07:28 AM -----



**rdenison@environmentald
efense.org**

05/17/2004 10:00 AM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Sarah_McLallen@americanchemistry.com

cc: luciarg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Phosphoric Acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine (CAS# 67763-14-8)

(Submitted via Internet 5/17/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, luciarg@msn.com and Sarah_McLallen@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Phosphoric Acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine (CAS# 67763-14-8).

The test plan and for phosphoric acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine (PAEHTD) was submitted by the Petroleum Additives Panel of the American Chemistry Council, which is comprised of ten member companies. This substance is formed from reacting phosphorous pentoxide with 2-ethylhexanol; this process also produces the corresponding dialkyl ester, and this mixture remains through various manufacturing steps and is used along with other additives to produce gear lubricants. The gear lubricants contain approximately 8% of PAEHTD and 6% of the dialkyl analog. The gear lubricants, according to the test plan, are further formulated into finished automotive gear oils that contain roughly 1% PAEHTD and smaller amounts of the dialkyl analog. No information was provided on environmental or human exposures.

This is an unusual test plan in that there are apparently no data on any of the SIDS endpoints for PAEHTD and thus there are no robust summaries. The sponsor indicates in the test plan that the knowledge gaps will be filled by conducting studies or by including PAEHTD in a category for which data are available for at least some of the members. We find the test plan incomplete and not reviewable because the potential category members are not identified. We would be pleased to evaluate and provide comments on a test plan that indicates the scope of the studies to be conducted, identifies the structural analogs to be used in the read-across approach, and provides robust summaries of the toxicological studies on those analogs. In any event, we agree with the sponsor that data need to be obtained for each of the SIDS endpoints.

Other comments are as follows:

1. The composition of the test substance used for the new studies needs to be carefully considered. We recommend that the material used be either the product of the reaction between phosphorous pentoxide and 2-ethylhexanol (which contains 55% PAEHTD, 35% dialkyl analog and 10% residual tertiary alkylamine) or the mixture used to prepare gear oil packages (which

RECEIVED
OPPT/NCIC
04 MAY 18 PM 1:04

contains 8% PAEHTD and 6% dialkyl analog, along with the other unspecified additives). These real-life mixtures will yield data of more toxicological relevance than from testing PAEHTD alone.

2. In order to minimize the use of animals in new studies, we recommend that a combined repeat dose/reproductive/developmental toxicity study be conducted. Also, the studies used to select doses for the combined study should be able to provide information adequate to satisfy the acute toxicity endpoint for the PAEHTD mixture.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense